

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

**TRANSLATION**  
**PCT**

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:

Date of mailing  
(day/month/year)

Applicant's or agent's file reference

**GP05-1005PCT**

**FOR FURTHER ACTION**

See paragraph 2 below

International application No.

**PCT/JP2005/006634**

International filing date (day/month/year)

**05.04.2005**

Priority date (day/month/year)

**16.04.2004**

International Patent Classification (IPC) or both national classification and IPC

Applicant

**OKABE, Hidetoshi**

1. This opinion contains indications relating to the following items:

- |                                     |              |  |
|-------------------------------------|--------------|--|
| <input checked="" type="checkbox"/> | Box No. I    | Basis of the opinion   |
| <input type="checkbox"/>            | Box No. II   | Priority   |
| <input type="checkbox"/>            | Box No. III  | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability   |
| <input type="checkbox"/>            | Box No. IV   | Lack of unity of invention   |
| <input checked="" type="checkbox"/> | Box No. V    | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability: citations and explanations supporting such statement |
| <input type="checkbox"/>            | Box No. VI   | Certain documents cited  |
| <input checked="" type="checkbox"/> | Box No. VII  | Certain defects in the international application   |
| <input type="checkbox"/>            | Box No. VIII | Certain observations on the international application  |

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/JP

Authorized officer

Facsimile No.

Telephone No.

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Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.  
☐ This opinion has been established on the basis of a translation from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material  
☐ a sequence listing  
☐ table(s) related to the sequence listing
  - b. format of material  
☐ in written format  
☐ in computer readable form
  - c. time of filing/furnishing  
☐ contained in the international application as filed.  
☐ filed together with the international application in computer readable form.  
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

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Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	<u>1-12</u>	YES
	Claims	<u></u>	NO
Inventive step (IS)	Claims	<u></u>	YES
	Claims	<u>1-12</u>	NO
Industrial applicability (IA)	Claims	<u>1-12</u>	YES
	Claims	<u></u>	NO

2. Citations and explanations:

Document 1: Shari A. PRICE-SCHIAVI, RAT MUC4 REDUCES BINDING OF ANTI-ERBB2 ANTIBODIES TO TUMOR CELL SURFACES, A POTENTIAL MECHANISM FOR HERCEPTIN RESISTANCE, International Journal of Cancer, Vol. 99, 2002, p783-791, see Abstract

Claims 1-12

Document 1 describes that the HER2/c-erbB-2 antibody called herceptin is effective for breast cancer of high expression of HER2/c-erbB-2, and that the bonding of the said antibody to HER2/c-erbB-2 is hindered by Muc4. (see Abstract etc.)

If so, it could be easily practiced by a person skilled in the art to try a test of the effectiveness of a herceptin therapy as to how much interfering Muc4 exists will influence the effectiveness in order to check whether or not the said herceptin can be bonded to its target HER2/c-erbB-2, in addition to checking whether or not HER2/c-erbB-2 has high expression.

Therefore, claims 1-12 do not appear to involve an inventive step.

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Box No. VII      Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

(1) Claims 11 and 12 are the inventions related to a reagent and reagent kit. But the descriptions of claim 11 and 12 refer to an examination method. So, the structure of reagent and reagent kit is not clear.